

WE CLAIM:

1. A method of treating gastroduodenal disease in a mammal,
said method comprising administering a therapeutically
effective amount of a composition comprising Helicobacter
urease peptides.
2. The method of claim 1 wherein said gastroduodenal disease is
gastritis.
3. The method of claim 1 wherein said gastroduodenal disease is
peptic ulcer disease.
4. The method of claim 1 wherein said gastroduodenal disease is
chronic dyspepsia with severe erosive gastroduodenitis.
5. The method of claim 1 wherein said gastroduodenal disease is
refractory non-ulcer dyspepsia.
6. The method of claim 1 wherein said gastroduodenal disease is
intestinal metaplasia.
7. The method of claim 1 wherein said gastroduodenal disease is
low grade MALT lymphoma.

8. The method of claim 1 wherein said gastroduodenal disease is Helicobacter infection.

9. The method of claim 1 wherein said gastroduodenal disease is Helicobacter pylori infection.

10. The method of claim 1 wherein said gastroduodenal disease is H. felis disease.

11. The method of claim 1 wherein said mammal is human.

12. The method of claim 1 wherein said composition comprises Helicobacter urease.

13. The method of claim 1 wherein said composition comprises the ure B subunit of Helicobacter urease.

14. The method of claim 1 wherein said composition comprises the ure B subunit of Helicobacter pylori urease.

15. The method of claim 1 further comprising administering said composition to a mucosal surface.

16. The method of claim 1 wherein said composition is administered orally, nasally, rectally, or ocularly.
17. The method of claim 1 further comprising administering said composition in a dosage ranging from 100 μ g to 1g.
- 5 18. The method of claim 17 further comprising administering said dosage over three to eight doses for a primary immunization schedule over one month.
19. The method of claim 1 wherein said composition is administered in association with a mucosal adjuvant.
- 10 20. The method of claim 19 wherein said mucosal adjuvant is selected from the group consisting of procholera genoid; cholera toxin B subunit fungal polysaccharides, including schizophyllan; muramyl dipeptide; muramyl dipeptide derivatives; phorbol esters; liposomes; microspheres; non-Helicobacter pylori bacterial lysates; labile toxin of Escherichia coli; block polymers; saponins; and ISCOMs.
- 15 21. The method of claim 1 wherein said urease peptides are genetically or chemically linked to a mucosal adjuvant.

22. The method of claim 21, wherein said mucosal adjuvant is the cholera toxin B subunit.
23. The method of claim 1 wherein said composition is administered in association with a carrier such that the composition is delivered in particulate form.
24. The method of claim 23 wherein said carrier is hydroxyapatite.
25. The method of claim 1 wherein said composition is administered in association with a microsphere carrier.
26. The method of claim 25 wherein said microsphere carrier is a polylactide-coglycolide biodegradable microsphere carrier.
27. The method of claim 1 wherein said composition comprises a recombinant live vector or a recombinant carrier system which expresses a Helicobacter urease peptide.
28. The method of claim 27 wherein said live vector is selected from the group consisting of Salmonella typhimurium, Salmonella typhi, Shigella, Bacillus, Lactobacillus, BCG,

Escherichia coli, Vibrio Cholerae, Campylobacter, Yeast, Herpes virus, Adenovirus, Poliovirus, Vaccinia, and Avipox.

29. The method of claim 27 wherein said carrier system is selected from the group consisting of Bluetongue virus-like particles, Rotavirus virus-like particles and Ty particles.
30. The method of claim 27 wherein said live vector or carrier system is administered to a mucosal surface.
31. A method of treating a human infected with Helicobacter pylori, said method comprising orally administering a therapeutically effective amount of a composition comprising the ure B subunit of Helicobacter pylori urease, in association with a mucosal adjuvant selected from the group consisting of procholeraegenoid; cholera toxin B subunit fungal polysaccharides, including schizophyllan; muramyl dipeptide; muramyl dipeptide derivatives; phorbol esters; liposomes; microspheres; non-Helicobacter pylori bacterial lysates; labile toxin of Escherichia coli; block polymers; saponins; and ISCOMs; said composition administered in particulate form in association with hydroxyapatite.

32. A method of treating a human infected with Helicobacter pylori, said method comprising orally administering a therapeutically effective amount of a composition comprising the ure B subunit of Helicobacter pylori urease in the form of a fused protein, genetically linked to the cholera toxin B subunit, said composition administered in particulate form in association with hydroxyapatite.

33. A method of treating a mammal infected with Helicobacter, said method comprising administering a therapeutically effective amount of a composition comprising peptides that display epitopes sufficiently homologous to epitopes displayed by Helicobacter urease such that antibodies that recognize epitopes displayed by Helicobacter urease will recognize epitopes displayed by said peptides.

34. A method of treating gastroduodenal disease in a mammal, said method comprising administering a therapeutically effective amount of a composition comprising an antibody that recognizes Helicobacter urease.

35. The method of claim 34 wherein said gastroduodenal disease is Helicobacter infection.

36. The method of claim 34 wherein said gastroduodenal disease is Helicobacter pylori infection.
37. The method of claim 34 wherein said mammal is human.
38. The method of claim 34 wherein said antibody is specific for Helicobacter pylori urease.
39. The method of claim 34 wherein said antibody is specific for the ure B subunit of Helicobacter pylori urease.
40. The method of claim 34 wherein said antibody is a monoclonal antibody.
41. The method of claim 34 wherein said antibody is an IgA antibody.
42. A method of treating a human infected with Helicobacter pylori, said method comprising administering a therapeutically effective amount of a composition comprising an IgA monoclonal antibody that recognizes the ure B subunit of Helicobacter pylori urease.

43. A method of treating a mammal infected with Helicobacter, said method comprising administering a therapeutically effective amount of a composition comprising anti-idiotypic antibodies to Helicobacter urease.

5 44. A composition useful in the therapeutic treatment of gastroduodenal disease, said composition comprising Helicobacter urease peptides.

45. The composition of claim 44 wherein said gastroduodenal disease is gastritis.

10 46. The composition of claim 44 wherein said gastroduodenal disease is peptic ulcer disease.

47. The composition of claim 44 wherein said gastroduodenal disease is chronic dyspepsia with severe erosive gastroduodenitis.

15 48. The composition of claim 44 wherein said gastroduodenal disease is refractory non-ulcer dyspepsia.

49. The composition of claim 44 wherein said gastroduodenal disease is intestinal metaplasia.

50. The composition of claim 44 wherein said gastroduodenal disease is low grade MALT lymphoma.

51. The composition of claim 44 wherein said gastroduodenal disease is Helicobacter infection.

5 52. The composition of claim 44 wherein said gastroduodenal disease is Helicobacter pylori infection.

53. The composition of claim 44 wherein said gastroduodenal disease is Helicobacter felis disease.

54. The composition of claim 44 wherein said mammal is human.

55. The composition of claim 44 wherein said Helicobacter urease peptides comprise Helicobacter urease.

56. The composition of claim 44 wherein said Helicobacter urease peptides comprise the ureB subunit of Helicobacter urease.

57. The composition of claim 44 wherein said Helicobacter urease peptides comprise Helicobacter pylori urease.

58. The composition of claim 44 wherein said Helicobacter urease comprise the ure B subunit of Helicobacter pylori urease.

59. The composition of claim 44 further comprising a mucosal adjuvant.

5 60. The composition of claim 59 wherein said mucosal adjuvant is selected from the group consisting of procholera toxin B subunit; cholera toxin B subunit; fungal polysaccharides, including schizophyllan; muramyl dipeptide; muramyl dipeptide derivatives; phorbol esters; liposomes; microspheres; non-Helicobacter pylori bacterial lysates; labile toxin of Escherichia coli; block polymers; saponins; and ISCOMs.

61. The composition of claim 44 wherein said urease peptides are genetically or chemically linked to a mucosal adjuvant.

62. The composition of claim 61, wherein said mucosal adjuvant is cholera toxin B subunit.

63. The composition of claim 44 further comprising a carrier such that the composition can be delivered in particulate form.

64. The composition of claim 44 wherein said carrier is hydroxyapatite.

65. The composition of claim 44 further comprising a microsphere carrier.

5 66. The composition of claim 65, wherein said microsphere carrier is a polylactide-coglycolide biodegradable microsphere carrier.

67. The composition of claim 44 wherein said composition comprises a recombinant live vector or a recombinant carrier system which expresses a Helicobacter urease peptide.

10 68. The composition of claim 67 wherein said live vector is selected from the group consisting of Salmonella typhimurium, Salmonella typhi, Shigella, Bacillus, Lactobacillus, BCG, Escherichia coli, Vibrio cholerae, Campylobacter, Yeast, Herpes virus, Adenovirus, Poliovirus, 15 Vaccinia, and Avipox.

69. The composition of claim 67 wherein said carrier system is selected from the group consisting of Bluetongue virus-like particles, Rotavirus virus-like particles, and Ty particles.

70. A composition useful in the therapeutic treatment of Helicobacter pylori infection of a human, said composition comprising the ure B subunit of Helicobacter pylori urease, a mucosal adjuvant selected from a group consisting of procholeraegenoid; cholera toxin B subunit fungal polysaccharides, including schizophyllan; muramyl dipeptide; muramyl dipeptide derivatives; phorbol esters; liposomes; microspheres; non-Helicobacter pylori bacterial lysates; labile toxin of Escherichia coli; block polymers; saponins; and ISCOMs, and further comprising hydroxyapatite.
71. A composition useful in the therapeutic treatment of Helicobacter pylori infection of a human, said composition comprising the ure B subunit of Helicobacter pylori urease in the form of a fused protein, genetically linked to the cholera toxin B subunit and hydroxyapatite, in particulate form.
- (72). A composition useful for the therapeutic treatment of a mammal infected with Helicobacter, said composition comprising peptides that display epitopes sufficiently homologous to epitopes displayed by Helicobacter urease such that antibodies that recognize epitopes displayed by

Helicobacter urease will recognize epitopes displayed by said peptides.

73. A composition useful for the therapeutic treatment of a mammal infected with Helicobacter said composition comprising anti-idiotypic antibodies to Helicobacter urease.

74. A composition useful in the therapeutic treatment of gastroduodenal disease, said composition comprising an antibody that recognizes Helicobacter urease.

75. The composition of claim 74 wherein said gastroduodenal disease is Helicobacter infection.

76. The composition of claim 74 wherein said gastroduodenal disease is Helicobacter pylori infection.

77. The composition of claim 74 wherein said gastroduodenal disease is Helicobacter felis disease.

78. The composition of claim 74 wherein said mammal is human.

79. The composition of claim 74 wherein the antibody is specific for Helicobacter pylori urease.

80. The composition of claim 74 wherein the antibody is specific for the ure B subunit of Helicobacter pylori urease.

81. The composition of claim 74 wherein the antibody is a monoclonal antibody.

5 82. The composition of claim 74 wherein the antibody is an IgA antibody.

83. A composition useful in the therapeutic treatment of gastroduodenal disease, said composition comprising an IgA monoclonal antibody that recognizes the ure B subunit of Helicobacter pylori urease and a mucosal adjuvant.

10 84. A method of preventing Helicobacter pylori infection of a human, said method comprising orally administering a prophylactically effective amount of a composition comprising Helicobacter pylori urease, in association with a mucosal adjuvant selected from the group consisting of prochole-
15 agenoid; cholera toxin B subunit; fungal saccharides, including schizophyllan; muramyl dipeptide; muramyl dipeptide derivatives; phorbol esters; liposomes; microspheres; non-Helicobacter pylori bacterial lysates; labile toxin of
20 Escherichia coli; block polymers; saponins; and ISCOMs, said

composition administered in particulate form in association with hydroxyapatite.

85. A method of preventing Helicobacter pylori infection of a human, said method comprising orally administering a prophylactically effective amount of a composition comprising Helicobacter pylori urease, in association with a mucosal adjuvant selected from the group consisting of procholesterol-agenoid; cholera toxin B subunit; fungal saccharides, including schizophyllan; muramyl dipeptide; muramyl dipeptide derivatives; phorbol esters; liposomes; microspheres; non-Helicobacter pylori bacterial lysates; labile toxin of Escherichia coli; block polymers; saponins; and ISCOMs, said composition administered in particulate form in association with hydroxyapatite.

86. A method of preventing Helicobacter pylori infection of a human, said method comprising orally administering a prophylactically effective amount of a composition comprising Helicobacter pylori urease in the form of a fused protein, genetically linked to the cholera toxin B subunit, said composition administered in particulate form, in association with hydroxyapatite.

5 87. A composition useful in preventing Helicobacter pylori
infection of a human, said composition comprising
Helicobacter pylori urease, in association with a mucosal
adjuvant selected from the group consisting of procholer-
agenoid; cholera toxin B subunit; fungal polysaccharides,
including schizophyllan; muramyl dipeptide; muramyl dipep-
tide derivatives; phorbol esters; liposomes; microspheres;
non-Helicobacter pylori bacterial lysates; labile toxin of
Escherichia coli; block polymers; saponins; and ISCOMs, said
10 composition present in particulate form in association with
hydroxyapatite.

15 88. A composition useful in preventing Helicobacter pylori
infection of a human, said composition comprising
Helicobacter pylori urease in the form of a fused protein,
genetically linked to the cholera toxin B subunit, said
fused protein present in particulate form, in association
with hydroxyapatite.